"3. A drug is misbranded unless its labeling bears 'adequate directions for use' (21 U. S. C. A., Section 352 (f)).

"4. The requirement that the labeling bear 'adequate directions for use' requires not only that the labeling bear statement of the dosage or the amount which is recommended that the consumer use, but also a statement of the purpose, namely, the disease or the effect upon the structure or function of the body for which the article of drug is to be taken.

"5. That directions for use are not adequate unless the purpose for which the drug is to be taken, as well as the amount to be taken, appear on the labeling.

"6. That the labels on the five articles of drug seized herein do not bear a statement of the disease or of the effect on the structure or function of the body of man, for which the said articles of drug are to be used, and therefore the labeling does not bear adequate directions for use.

"7. That the labeling is misleading.

"8. That the said articles of drug seized herein are misbranded.

"9. That the said articles of drug seized herein are subject to forfeiture and condemnation to the United States.

"10. Because of the facts heretofore found, libelant is entitled to a decree of condemnation and forfeiture.

"11. That the articles of drug seized herein were seized in the Eastern Judicial District, Eastern Division, of Missouri, and that the Court has jurisdiction over this cause by virtue of Section 334, Title 21, U. S. C. A.

"12. That as no showing has been made that the said articles of drug seized herein have any value or can be sold without violating the Federal Food, Drug and Cosmetic Act, and any State or local law, the said articles of drug shall be destroyed by the United States Marshal.

"13. Libelant is entitled to its costs herein.

"14. Under the facts heretofore found and the law, it is not necessary to pass upon the validity of the regulation, 2.106a1, of the Administrator of the Food and Drug Administration, or to make any findings of fact as to the advertising disseminated by the claimant herein, or to determine the customary conditions of purchase and use of the said articles of drug."

In accordance with the above findings and conclusions, a decree was entered on July 11, 1947, forfeiting the products to the United States and directing that they be destroyed. On July 21, 1947, the claimant filed a motion for a new trial and to amend the findings of fact and conclusions of law. After considering the briefs of the parties, the court, on March 23, 1948, overruled the claimant's motion for a new trial; and on August 4, 1948, the court ordered that the decree for destruction of the products be executed.

2406. Misbranding of pile pipes. U. S. v. 702 * * *. (F. D. C. No. 24347. Sample No. 26662–K.)

LIBEL FILED: February 17, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 18, 1946, by the Victor Metal Products Corp., from Brooklyn, N. Y.

PRODUCT: 702 *pile pipes* at St. Louis, Mo. Examination showed that the pipes were plastic tubes which were threaded at one end to attach to collapsible tubes of ointment.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: March 18, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2407. Adulteration and misbranding of Gaduplex and Vibeta Elixir with Iron. U. S. v. Columbus Pharmacal Co., Freeman A. Rostofer, and Robert N. Fullerton. Pleas of guilty. Fine of $600 against each defendant. (F. D. C. No. 24267. Sample Nos. 53833–H, 83283–H.)

INFORMATION FILED. June 15, 1948, Southern District of Ohio, against the Columbus Pharmacal Co., a corporation, Columbus, Ohio, and Freeman A. Rostofer, president, and Robert N. Fullerton, vice-president.

ALLEGED SHIPMENT: On or about December 18, 1946, and July 14, 1947, from the State of Ohio into the State of Kentucky.

NATURE OF CHARGE: *Gaduplex.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since each fluid ounce of the article was represented to supply approximately 4.5 milligrams of vitamin B_1, equivalent to 1,500 International Units of vitamin B_1, and to supply approximately 60 milligrams of niacin, whereas each fluid ounce of the article supplied a lesser amount of vitamin B_1 and niacin. Misbranding, Section 502 (a), the label statement "Each Fluidounce Supplies Approximately * * * Vitamin B_1 (Thiamin) (1,500 I. U.) 4.5 mg. * * * Niacin . . . 60.0 mg." was false and misleading.

Vibeta Elixir with Iron. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since each fluid ounce of the article was represented to contain 3 milligrams of vitamin B_1, equivalent to 1,000 International Units of vitamin B_1, whereas each fluid ounce of the article contained a lesser amount of vitamin B_1. Misbranding, Section 502 (a), the label statement "Each Fluidounce Represents * * * Vitamin B_1 . . . (1,000 I. U.) 3 mg." was false and misleading.

DISPOSITION: June 18, 1948. Pleas of guilty having been entered, the court imposed a fine of $600 against each defendant.

2408. Adulteration and misbranding of estrogenic substance. U. S. v. Halfdan Hebo. Plea of not guilty. Tried to the jury; verdict of guilty. Fine of $500 on count 1; imposition of sentence suspended on count 2; defendant placed on probation for 2 years. (F. D. C. No. 17816. Sample No. 54877–F.)

INFORMATION FILED: January 30, 1947, Southern District of New York, against Halfdan Hebo, New York, N. Y.

ALLEGED SHIPMENT: On or about September 11, 1944, from the State of New York into the State of Wisconsin.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), an inert compound, cholesterol, had been substituted in part for estrogenic substance.

Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and, Section 502 (i) (3), it was offered for sale under the name of another drug, in that it was offered for sale under the name "Estrogenic Substance From Pregnant Mares' Urine."

DISPOSITION: March 6, 1947. A plea of not guilty having been entered, the case came on for trial before a jury. At the conclusion of the trial, the jury returned a verdict of guilty. Thereupon, the court imposed a fine of $500 on count 1 of the information relating to the adulteration of the product, suspended the imposition of sentence on count 2 relating to the charge of misbranding, and placed the defendant on probation for 2 years.

2409. Adulteration and misbranding of estrogenic substance in sesame oil and misbranding of estrogenic substance powder. U. S. v. Hema Drug Co., Inc. Plea of guilty. Fine, $525. (F. D. C. No. 16572. Sample Nos. 85231–F, 31201–H.)

INFORMATION FILED: March 27, 1946, Eastern District of New York, against the Hema Drug Co., Inc., Maspeth, N. Y.

ALLEGED SHIPMENT: On or about November 27, 1944, from the State of New York into the States of California and Pennsylvania.

LABEL, IN PART: "Estrogenic Substance Powder," or "Estrogenic Substance In Sesame Oil." The latter was invoiced as "Natural Estrogenic Hormone in Sesame Oil."

NATURE OF CHARGE: *Estrogenic substance in sesame oil.* Adulteration, Section 501 (d), substances other than natural estrogenic hormone in sesame oil had been substituted in whole or in part for natural estrogenic hormone in sesame oil, which the article was represented to be.

Both products. Misbranding, Section 502 (e) (2), the articles were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients, and the labels failed to bear the common or usual name of each active ingredient of the articles.

DISPOSITION: July 8, 1948. A plea of guilty having been entered, the court imposed a fine of $175 on each of the 3 counts of the information.